Re: GRAS Notice No. GRN 000815

Dear Dr. Röhrig:

We are issuing a second revised copy of the response letter for GRN 000815. The original letter for this GRAS notice was signed on August 20, 2019. In an email dated January 15, 2020, Dr. Marta H. Miks of Glycom A/S (Glycom) informed us of an omission in the discussion of the ingredient specifications in our letter. In her email, Dr. Miks also informed us that the exposure estimates for the notified ingredient in infants were incorrectly reported in the notice. In an email dated February 5, 2020, we requested that Glycom submit a supplement stating the correct exposure estimates and discussing any related impact on the safety conclusion described in the notice. Glycom submitted a supplement on March 26, 2020. In response to the information about our omission, we included the specification for lactose on page 2, paragraph 3 of our letter. In response to the supplement, we corrected errors in the exposure estimates for the notified ingredient in infants on page 3, paragraph 1 of our letter. In a new footnote on page 4 of our letter, we included your statement that the corrected exposure estimates do not change your safety conclusion. This first revised response letter was signed on May 7, 2020.

In emails dated June 4, 2020 and June 17, 2020, Ms. Annette Lau of Glycom requested that we update the revised response letter to clarify the microbial limits when 2'-FL/DFL is used in liquid infant formulas that require a retort step. In a new footnote on page 2 of our letter, we included a statement noting that the limits for Listeria monocytogenes and Cronobacter sakazakii, were not needed and the limit for Enterobacteriaceae would be <10 CFU/g when 2'-FL/DFL is used in liquid infant formulas that require a retort step.
If you have any questions, please contact me by electronic mail at Ellen.Anderson@fda.hhs.gov or by telephone at 240-402-1309.

Sincerely,

Ellen T. Anderson

Ellen Anderson
Division of Food Ingredients
Center for Food Safety and Applied Nutrition